FEB 13 2012

# 5. 510(k) Summary

**Device Trade Name:** coflex-F Implant System

**Manufacturer:**
Paradigm Spine, LLC
505 Park Avenue, 14th Floor
New York, NY 10022

**Contact:**
Ms. Michelle McDonough
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
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**Date Prepared:** February 10, 2012

**Classification:** 21 CFR 888.3050, Spinal interlaminal fixation orthosis

**Class:** II

**Product Code:** KWP

**Indications For Use:**
The coflex-F Implant System is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies – with up to Grade 1 spondylolisthesis.

**Device Description:**
The coflex-F Implant System is a spinous process fixation device that stabilizes the spinous processes and spine to act as an adjunct to fusion. It consists of a single, U-shaped component, fabricated from medical grade titanium alloy (Ti6Al4V). A set of two wings extends vertically from the superior long arm of the device, with a second set of wings extending below the inferior long arm. A screw and sleeve are inserted through a prepared hole and fixes the crimped wings to the superior and inferior spinous processes.

The purpose of this Special 510(k) is to add small- and medium-sized coflex-F Short devices to the coflex-F Implant System. The modifications are intended to allow the operating surgeon to better accommodate various patient anatomies. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

**Predicate Device(s):**
The modified coflex-F Short is substantially equivalent to the predicate coflex-F Implant (Paradigm Interspinous Fusion Plate) previously cleared in K093438 with respect to indications, design, function, and materials.

**Substantial Equivalence:**
Finite element analysis and engineering rationale demonstrated that the addition of new components did not introduce a new worst case. Additionally, biocompatibility tests per ISO 10993 (i.e., irritation and sensitization) were conducted on materials used for device-specific instruments. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met and the coflex-F Short is substantially equivalent to the predicate device(s).

**Conclusion:**
The coflex-F Short is substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Paradigm Spine, LLC
% Musculoskeletal Clinical Regulatory
Advisers, LLC
Ms. Michelle McDonough
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K112595
Trade/Device Name: coflex-F Implant System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 20, 2011
Received: December 21, 2011

Dear Ms. McDonough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson
DSP CLN D.1

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4. Indications for Use

510(k) Number (if known): K112595

Device Name: coflex-F Implant System

The coflex-F Implant System is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies – with up to Grade 1 spondylolisthesis.

| Prescription Use ___√___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112595